Application Number:

10/565,573

Amendment Dated:

November 23, 2010

Office Action Dated:

May 21, 2010

## **REMARKS**

This is in response to the Office Action dated May 21, 2010 for which a three (3) month period of response was given. A Petition and fee under 37 C.F.R. § 1.137(b) accompany this paper. Should any additional petition fees and/or additional claims fees be due, the Commissioner is hereby authorized to treat this paper as authorization and/or a Petition to charge any fees due to Deposit Account No. 50-0959, Attorney Docket No. 089498.0480.

Claims 1, 3, 4, 6 through 9 and 11 through 25 are pending in the present application. Claims 2, 5 and 10 were cancelled previously. Claims 1, 4, 11, 18 and 22 have been amended for clarification purposes. Support for the amendments to claims 1, 4, 11, 18 and 22 exist in the specification as filed. As such, entry and consideration of the amended claims and the remarks which follow, is believed due and is respectfully requested.

## <u>I.</u> The Objection to the Abstract:

The Examiner has objected to the Abstract. In light of this, the undersigned has provided a new Abstract that addresses the issues raised by the Examiner in the Office Action mailed May 21, 2010. As such, the objection to Abstract is now believed to have been rendered moot. Accordingly, acceptance of the revised Abstract is believed due and is respectfully requested.

#### II. The Claim Objections:

Claims 11, 12 and 15 through 17 have been objected to in light of claim 11 being dependent upon a cancelled claim. In light of this objection, claim 11 has been amended to depend from claim 7. Accordingly, the claim objection of claims 11, 12 and 15 through 17 is believed to have been rendered moot, and withdrawal thereof is believed due and is respectfully requested.

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### III. The 35 U.S.C. § 102/35 U.S.C. § 103(a) Rejections:

Claim 4 has been rejected under 35 U.S.C. § 102(b), or in the alternative under 35 U.S.C. § 103(a), over Abrams (United States Patent No. 2,844,546). Abrams discloses cation exchange resins and to the preparation of resin matrices. The Examiner points to column 7, lines 35 through 75 and column 8, lines 1 through 19 and lines 65 through 72 as pertinent to pending claim 4. In these passages, Abrams discloses producing a cation exchange resin matrix which upon oxidation produces nitric oxide as a by-product.

However, as is clear from the disclosure of Abrams, Abrams does not disclose, teach or suggest a method for producing nitric oxide comprising: producing nitric oxide by using a combination of an ionic exchange resin and a salt, wherein the ionic exchange resin is a cationic exchange resin and wherein the cationic exchange resin has a hydrogen-atom counter ion (emphasis supplied). Since Abrams does not disclose each an every feature of pending claim 4, Abrams cannot anticipate, or render obvious, pending claim 4. As such, withdrawal of the 35 U.S.C. § 102(b)/35 U.S.C. § 103(a) rejection of claim 4 over Abrams is believed due and is respectfully requested.

Claim 4 has been rejected under 35 U.S.C. § 102(b), or in the alternative under 35 U.S.C. § 103(a), over Zhang et al. (<u>An Integrated Nitric Oxide Sensor Based on Carbon Fiber Coated with Selective Membranes</u> – Electroanalysis 2000, 12, No. 14. pp. 1113 to 1117). Zhang et al. discloses a method to measure nitric oxide in vivo using No sensors. The Examiner contends that Zhang et al. discloses a method to produce nitric oxide via the use of an ion exchange resin.

However, as is clear from the disclosure of Zhang et al., Zhang et al. does not disclose, teach or suggest a method for producing nitric oxide comprising: producing nitric oxide by using a combination of an ionic exchange resin and a salt, wherein the ionic exchange resin is a cationic exchange resin and wherein the cationic exchange resin has a hydrogen-atom counter ion (emphasis supplied). Since Zhang et al. does not disclose each an every feature of pending claim 4, Zhang et al. cannot anticipate, or render obvious, pending claim 4. As such, withdrawal of the 35 U.S.C. § 102(b)/35 U.S.C. § 103(a) rejection of claim 4 over Zhang et al. is believed due and is respectfully requested.

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Claims 1 and 3 have been rejected under 35 U.S.C. § 102(a), or in the alternative under 35 U.S.C. § 103(a), over Batchelor et al. (United States Patent Application Publication No. 2002/0115559 A1). Batchelor et al. discloses biocompatible materials that have the ability to release nitric oxide (NO) in situ at the surface-blood interface when in contact with blood. The Examiner points to Paragraphs [0039] through [0041] of Batchelor et al.

However, as is clear from the disclosure of Batchelor et al., Batchelor et al. does not disclose, teach or suggest a method for producing nitric oxide comprising: producing nitric oxide by using a combination of an ionic exchange resin and a salt, wherein the ionic exchange resin is an anionic exchange resin (emphasis supplied). Since Batchelor et al. does not disclose each an every feature of pending claim 1, Batchelor et al. cannot anticipate, or render obvious, pending claims 1 and 3. As such, withdrawal of the 35 U.S.C. § 102(a)/35 U.S.C. § 103(a) rejection of claims 1 and 3 over Batchelor et al. is believed due and is respectfully requested.

Claims 1, 3, 18, 19, 21, 22 and 24 have been rejected under 35 U.S.C. § 102(b), or in the alternative under 35 U.S.C. § 103(a), over Smith et al. (<u>Nitric Oxide-Releasing Polymers Containing the [N(O)NO]</u> Group, Journal Med. Chem., 1996, 39, pp. 1148 to 1156). Smith et al. discloses the synthesis of polymer structures having [N(O)NO] groups.

However, as is clear from the disclosure of Smith et al., Smith et al. does not disclose, teach or suggest a method for producing nitric oxide that utilizes either: (1) an ionic exchange resin and a salt, or (2) a pH adjuster and a salt which are added to a nanofiber having a diazeniumdiolate functional group (emphasis supplied). Since Smith et al. does not disclose each an every feature of pending claims 1, 18 and 22, Smith et al. cannot anticipate, or render obvious, pending claims 1, 3, 18, 19, 21, 22 and 24. As such, withdrawal of the 35 U.S.C. § 102(b)/35 U.S.C. § 103(a) rejection of claims 1, 3, 18, 19, 21, 22 and 24 over Smith et al. is believed due and is respectfully requested.

Claims 1 and 3 have been rejected under 35 U.S.C. § 102(b), or in the alternative under 35 U.S.C. § 103(a), over WO 98/13358. WO 98/13358 discloses producing various nitric oxide-containing compounds.

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However, as is clear from the disclosure of WO 98/13358, WO 98/13358 does not disclose, teach or suggest a method for producing nitric oxide comprising: producing nitric oxide by using a combination of an ionic exchange resin and a salt, wherein the ionic exchange resin is an anionic exchange resin (emphasis supplied). Since WO 98/13358 does not disclose each an every feature of pending claims 1, WO 98/13358 cannot anticipate, or render obvious, pending claims 1 and 3. As such, withdrawal of the 35 U.S.C. § 102(b)/35 U.S.C. § 103(a) rejection of claims 1 and 3 over WO 98/13358 is believed due and is respectfully requested.

Claims 1, 3, 6, 7, 11, 12, 18 and 21 through 24 have been rejected under 35 U.S.C. § 102(b), or in the alternative under 35 U.S.C. § 103(a), over WO 96/15797. WO 96/15797 discloses producing various polymeric compounds that are capable of releasing nitric oxide.

However, as is clear from the disclosure of WO 96/15797, WO 96/15797 does not disclose, teach or suggest a method for producing nitric oxide that utilizes either: (1) an ionic exchange resin and a salt, or (2) a pH adjuster and a salt which are added to a nanofiber having a diazeniumdiolate functional group (emphasis supplied). Since WO 96/15797 does not disclose each an every feature of pending claims 1, 7, 18 and 22, WO 96/15797 cannot anticipate, or render obvious, pending claims 1, 3, 6, 7, 11, 12, 18 and 21 through 24. As such, withdrawal of the 35 U.S.C. § 102(b)/35 U.S.C. § 103(a) rejection of claims 1, 3, 6, 7, 11, 12, 18 and 21 through 24 over WO 96/15797 is believed due and is respectfully requested.

Claims 18, 19, 22 and 23 have been rejected under 35 U.S.C. § 102(b), or in the alternative under 35 U.S.C. § 103(a), over Smith et al. (United States Patent No. 5,519,020). Smith et al. discloses water insoluble polymeric NONOate complexes which are capable of accelerating wound repair through the controlled therapeutic release of NO.

However, as is clear from the disclosure of Smith et al., Smith et al. does not disclose, teach or suggest a method for producing nitric oxide that utilizes a pH adjuster and a salt which are added to a nanofiber having a diazenium diolate functional group (emphasis supplied). Since Smith et al. does not disclose each an every feature of pending claims 18 and 22, Smith et al. cannot anticipate, or render obvious, pending claims 18, 19,

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22 and 23. As such, withdrawal of the 35 U.S.C. § 102(b)/35 U.S.C. § 103(a) rejection of claims 18, 19, 22 and 23 over Smith et al. is believed due and is respectfully requested.

## IV. The 35 U.S.C. § 103(a) Rejections:

Claims 8 and 9 have been rejected under 35 U.S.C. § 103(a) over WO 96/15797 as applied to claim 7, and further in view of Fine et al. (United States Published Patent Application No. 2003/0064028). The teachings and shortcomings of WO 96/15797 are discussed in detail above. Fine et al. discloses various methods for producing nitric oxide.

However, as can be seen therefrom, Fine et al. does not disclose the use of a combination of <u>ionic exchange resin and a salt to produce nitric oxide</u> (emphasis supplied). Given this, the Examiner has used impressible hindsight to reject claims 8 and 9. As such, claims 8 and 9 are non-obvious over the combination of WO 96/15797 and Fine et al. Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 8 and 9 over the combination of WO 96/15797 and Fine et al. is believed due and is respectfully requested.

Claims 7, 13 and 14 have been rejected under 35 U.S.C. § 103(a) over Abrams (United States Patent No. 2,844,546) in view of WO 96/15797. The teachings and shortcomings of both Abrams and WO 96/15797 are discussed in detail above.

However, as is clear from the disclosures of Abrams and WO 96/15797, both Abrams and WO 96/15797 do not disclose, teach or suggest a method for producing nitric oxide that utilizes an ionic exchange resin and a salt (emphasis supplied). Since both Abrams and WO 96/15797 do not disclose each an every feature of pending claim 7, Abrams and WO 96/15797 cannot render obvious pending claims 7, 13 and 14. As such, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 7, 13 and 14 over the combination of Abrams and WO 96/15797 is believed due and is respectfully requested.

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Claims 7, 13 and 14 have been rejected under 35 U.S.C. § 103(a) over Zhang et al. (An Integrated Nitric Oxide Sensor Based on Carbon Fiber Coated with Selective Membranes – Electroanalysis 2000, 12, No. 14. pp. 1113 to 1117) in view of WO 96/15797. The teachings and shortcomings of both Zhang et al. and WO 96/15797 are discussed in detail above.

However, as is clear from the disclosures of Zhang et al. and WO 96/15797, both Zhang et al. and WO 96/15797 do not disclose, teach or suggest a method for producing nitric oxide that utilizes an ionic exchange resin and a salt (emphasis supplied). Since both Zhang et al. and WO 96/15797 do not disclose each an every feature of pending claim 7, Zhang et al. and WO 96/15797 cannot render obvious pending claims 7, 13 and 14. As such, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 7, 13 and 14 over the combination of Zhang et al. and WO 96/15797 is believed due and is respectfully requested.

Claim 15 has been rejected under 35 U.S.C. § 103(a) over WO 96/15797 as applied to claims 7, 11 and 12, and further in view of Tucker et al. (United States Published Patent Application No. 2005/0036949). The teachings and shortcomings of WO 96/15797 are discussed in detail above. Tucker et al. discloses various methods of producing nitric oxide. However, Tucker et al. fails to cure the deficiencies of WO 96/15797.

This is because both WO 96/15797 and Tucker et al. do not disclose, teach or suggest a method for producing nitric oxide that utilizes an ionic exchange resin and a salt (emphasis supplied). Since both WO 96/15797 and Tucker et al. do not disclose each an every feature of pending claim 7, WO 96/15797 and Tucker et al. cannot render obvious pending claim 15. As such, withdrawal of the 35 U.S.C. § 103(a) rejection of claim 15 over the combination of WO 96/15797 and Tucker et al. is believed due and is respectfully requested.

Claim 16 has been rejected under 35 U.S.C. § 103(a) over WO 96/15797 as applied to claims 7, 11 and 12, and further in view of Benjamin et al. (United States Published Patent Application No. 2002/0136750). The teachings and shortcomings of WO 96/15797 are discussed in detail above. Benjamin et al. discloses various methods of producing nitric

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oxide. However, Benjamin et al. fails to cure the deficiencies of WO 96/15797.

This is because both WO 96/15797 and Benjamin et al. do not disclose, teach or suggest a method for producing nitric oxide that utilizes an ionic exchange resin and a salt (emphasis supplied). Since both WO 96/15797 and Benjamin et al. do not disclose each an every feature of pending claim 7, WO 96/15797 and Benjamin et al. cannot render obvious pending claim 15. As such, withdrawal of the 35 U.S.C. § 103(a) rejection of claim 15 over the combination of WO 96/15797 and Benjamin et al. is believed due and is respectfully requested.

Claim 17 has been rejected under 35 U.S.C. § 103(a) over WO 96/15797 as applied to claims 7, 11 and 12, and further in view of Smith et al. (United States Patent No. 5,519,020). The teachings and shortcomings of both WO 96/15797 and Smith et al. are discussed in detail above.

This is because both WO 96/15797 and Smith et al. do not disclose, teach or suggest a method for producing nitric oxide that utilizes an ionic exchange resin and a salt (emphasis supplied). Since both WO 96/15797 and Smith et al. do not disclose each an every feature of pending claim 7, WO 96/15797 and Smith et al. cannot render obvious pending claim 17. As such, withdrawal of the 35 U.S.C. § 103(a) rejection of claim 17 over the combination of WO 96/15797 and Smith et al. is believed due and is respectfully requested.

Claims 20 and 25 have been rejected under 35 U.S.C. § 103(a) over Smith et al. (Nitric Oxide-Releasing Polymers Containing the [N(O)NO] Group, Journal Med. Chem., 1996, 39, pp. 1148 to 1156) as applied to claims 18 and 22, and further in view of WO 01/54667. The teachings and shortcomings of Smith et al. are discussed in detail above. WO 01/54667 discloses various electrospun pharmaceutical compositions. However, WO 01/54667 fails to cure the deficiencies of Smith et al.

This is because, as is clear from the disclosures contained therein, both Smith et al. and WO 01/54667 do not disclose, teach or suggest a method for producing nitric oxide that utilizes a pH adjuster and a salt which are added to a nanofiber having a diazeniumdiolate functional group (emphasis supplied). Since both Smith et al. and WO

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01/54667 do not disclose each an every feature of pending claims 18 and 22, the combination of Smith et al. and WO 01/54667 cannot render obvious pending claims 20 and 25. As such, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 20 and 25 over the combination of Smith et al. and WO 01/54667 is believed due and is respectfully requested.

Claims 20 and 25 have been rejected under 35 U.S.C. § 103(a) over WO 96/15797 as applied to claims 18 and 22, and further in view WO 01/54667. The teachings and shortcomings of WO 96/15797 are discussed in detail above. WO 01/54667 discloses various electrospun pharmaceutical compositions. However, WO 01/54667 fails to cure the deficiencies of WO 96/15797.

This is because, as is clear from the disclosures contained therein, both WO 96/15797 and WO 01/54667 do not disclose, teach or suggest a method for producing nitric oxide that utilizes a pH adjuster and a salt which are added to a nanofiber having a diazeniumdiolate functional group (emphasis supplied). Since both WO 96/15797 and WO 01/54667 do not disclose each an every feature of pending claims 18 and 22, the combination of WO 96/15797 and WO 01/54667 cannot render obvious pending claims 20 and 25. As such, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 20 and 25 over the combination of WO 96/15797 and WO 01/54667 is believed due and is respectfully requested.

Claims 20 and 25 have been rejected under 35 U.S.C. § 103(a) over Smith et al. (United States Patent No. 5,519,020) as applied to claims 18 and 22, and further in view WO 01/54667. The teachings and shortcomings of Smith et al. are discussed in detail above. WO 01/54667 discloses various electrospun pharmaceutical compositions. However, WO 01/54667 fails to cure the deficiencies of Smith et al.

This is because, as is clear from the disclosures contained therein, both Smith et al. and WO 01/54667 do not disclose, teach or suggest a method for producing nitric oxide that utilizes a pH adjuster and a salt which are added to a nanofiber having a diazenium diolate functional group (emphasis supplied). Since both Smith et al. and WO 01/54667 do not disclose each an every feature of pending claims 18 and 22, the

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combination of Smith et al. and WO 01/54667 cannot render obvious pending claims 20 and 25. As such, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 20 and 25 over the combination of Smith et al. and WO 01/54667 is believed due and is respectfully requested.

# V. Conclusion:

Accordingly, reconsideration and withdrawal of the pending objection to the Abstract and the claims, as well as the various 35 U.S.C. § 102 and 35 U.S.C. § 103(a) rejections of claims 1, 3, 4, 6 through 9 and 11 through 25 is respectfully requested.

For at least the foregoing reasons, the present application is believed to be in condition for allowance, and a Notice of Allowance is respectfully requested.

Should the Examiner wish to discuss any of the foregoing in more detail, the undersigned attorney would welcome a telephone call.

Respectfully submitted,

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